

510(k) Summary of Safety and Effectiveness - as required by 21 CFR part 807.92

Date prepared: August, 22 2006

Submitted by: Amicas, Inc.
20, Guest St.
Boston, MA 02135

OCT 27 2006

Contact: Patrice Nedelec
Contact email: pnedelec@amicas.com
Contact Telephone: 617-779-7858 or 617-372-1331
Contact Fax: 617-783-7209 or 806-313-1214

Device Trade Name: Amicas Vision Series PACS 4.3
Device Common Name: Picture Archiving Communication System (PACS)
Regulation number: 892.2050
Device Classification: Class II
Name: Amicas Vision Series PACS
Predicate Device: Amicas Light Beam Diagnostic Workstation
Predicate Device Manufacturer: AMICAS Inc.
20 Guest Street
Boston, MA 021235
Predicate Device 510(k) number: K022970
Date received: 09/06/2002
Decision date: 11/22/2002
Decision: Substantially equivalent
Panel Code Device reviewed by: Radiology
Panel Code Device classified by: Radiology
Product Code: LLZ
Regulation number: 892.2050
Device Classification: Class II

Device Description and intended use:

AMICAS Vision Series PACS 4.3 is software intended to create and display two-dimensional and three-dimensional images of anatomy from a series of digitally acquired images.

Typical users of Vision PACS Series 4.3 are radiologists, technologists and clinicians.

Technological characteristics:

Feature	Amicas LightBeam Workstation (predicate)	Amicas Vision Series PACS 4.3
Software Only	Yes	Yes
Image Measurements	Yes	Yes
Multi-planar reformatting	Yes	Yes
Volume Rendering	Yes	Yes
Maximum Intensity Projection	Yes	Yes
Image editing	Yes	Yes
Printing	Yes	Yes
DICOM Images	Yes	Yes
Lossless JPEG2000 Compression	Yes	Yes
Lossy JPEG2000 Compression	Yes	Yes
DICOM Overlay supporting MQSA-requirements	No	Yes
DICOM Printing	No	Yes

General Safety Considerations

Amicas Vision Series 4.3 software and the computer platform that it is installed on together constitute a system for the interpretation of medical image data by trained and qualified professionals. It is the user's responsibility to ensure that image quality, display quality, environmental lighting and other possible distractions are consistent with the clinical application. Refer to the instruction manuals for your specific computer and display hardware for information regarding installation, calibration and additional safety issues.

Amicas Vision Series 4.3, as its predicate, includes tools for enlarging, highlighting and obscuring portions of an image relative to other portions. Inappropriate application of these tools can result in the obscuration of important anatomy and contribute to an erroneous interpretation. It is the user's responsibility to understand the effect of image manipulation tools and to apply in a manner consistent with the clinical application. The user must review the cautionary statements in the User's guide.

Be sure to limit access to patient data to authorized individuals who are fully trained and qualified to use this equipment.

Testing:

Amicas Vision Series 4.3 is tested with reference to its Software Requirements Specifications, as documented in the Verification Procedure included in this 510(k) filing.

Functional testing is an integral part of Amicas, Inc. Product Development process known as “VDEV” (Vision Development Elaboration Validation), also included in this filing (see section G).

The Amicas Compliance Department, per process, independently verifies completeness of all deliverables -to include testing reports and assessment of safety and effectiveness- before issuing release authorizations.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 27 2006

Ms. Patrice J.C. Nedelec
Director, Compliance
AMICAS, Inc.
20 Guest Street, Suite 200
BOSTON MA 02135

Re: K062477
Trade/Device Name: AMICAS Vision Series PACS 4.3
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 23, 2006
Received: August 24, 2006

Dear Mr. Nedelec:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062477

Device Name: AMICAS Vision Series PACS 4.3

Indications For Use:

Vision Series PACS 4.3 is designed and marketed for soft copy reading, communication, printing and storage of studies produced by digital modalities, to include Digital Mammography.

Vision Series PACS receives images acquired from DICOM-compliant medical imaging systems, data from FDA-cleared Computer-Aided Detection systems and other FDA-cleared Image processing systems.

Vision Series PACS imports images and render said images, upon request, within the AMICAS LightBeam Diagnostic Workstation utilizing both lossless (reversible) and lossy (irreversible) compression.

To support the diagnostic interpretation of Mammography studies, Vision Series PACS will display the full fidelity DICOM image in a non-compressed format. Images will be rendered with patient and clinical information clearly displayed as part of the DICOM Overlay as required by MQSA, on monitors cleared by FDA for use in Digital Mammography. Lossy compressed mammography images and digitized film screen images should not be used for the purpose of primary diagnosis. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Vision Series PACS formats and delivers images over a network to a FDA-cleared DICOM printer as requested and defined by the user.

Vision Series PACS must be installed on suitable, commercial-standard hardware.

It is the user's responsibility to ensure monitor quality, ambient light conditions and image compression ratios are consistent with the clinical application.

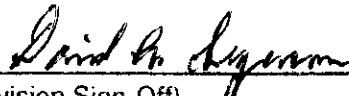
Prescription Use ☒
(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062477